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10/671,721	09/29/2003	Yuji Imaizumi	045070-5036	9270

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MORGAN LEWIS & BOCKIUS LLP
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WASHINGTON, DC 20004

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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05/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,721

Applicant(s)

IMAZUMI ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-31, 33, 34, 40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-31, 33, 34, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 25-31, 33, 34, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 25 and 30 have been amended and include newly recited structural elements including “photo-detecting means”; “a first extracting member”; “a second extracting member”; “a specifying member”; and “an analyzing member”. Support for these newly recited structural elements cannot be readily determined upon reviewing the originally filed disclosure. As a result, the specification fails to adequately convey to one of ordinary skill in the art that the instantly claimed invention was in the possession of the inventors at the time of the filing of the instant application. Note Applicants have not pointed out where the new (or amended) claim is supported, nor does there appear to be a written description of the claim limitations as discussed above in the application as filed (See M.P.E.P. 2163.04).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 25-31, 33, 34, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 25 and 30 appear to invoke 35 USC 112, sixth paragraph, with respect to the claimed “photo-detecting means”; “a first extracting member”; “a second extracting member”; “a specifying member” and “an analyzing member”. In view of the instant specification, it is not readily clear to one of ordinary skill in the art which of the disclosed structures provide the recited functions of the claims. As a result, the metes and bounds of the claims cannot be clearly determined. Note, page 23 of the instant specification implies that two different filter sets of a fluorescent microscope and image processing unit correspond to a “specifying means”, however, it would appear that additional structure would be required to perform the functions recited in the instant claims, such as the control unit. Additional review of the specification fails to clearly convey to one of ordinary skill in the art what structures, if any, correspond to the functions associated with the listed “means” or “members” recited in the instant claims. As a result, it is not readily apparent to one of ordinary skill in the art which structures of the instant specification perform the function recited in the means plus function recitations of the instant claims (See MPEP 2181). Note the claims including the language “member” rather than “means” have been construed as means-plus-function limitations invoking 35 U.S.C. 112, sixth paragraph since the claimed limitations were described in terms of their function not their mechanical structure.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 25-28, 30, 31, 33, 34 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Yao et al.(US 2003/0100059).

The reference of Yao et al. discloses an intracellular measuring apparatus for measuring intracellular reactions wherein the apparatus includes a specifying means in which the intensity of the first light emitted from the specimen in accordance with the presence of a stated protein is detected to specify a noted region of the specimen based on the first light and a selection means in which the intensity of second light emitted from the specimen in accordance with intracellular reactions induced by the protein is detected, of the detected intensity of the second light, the intensity of the second light emitted from the noted region. Specifically Example 1 discloses the use of a real-time fluorescence imaging device that is capable of distinguishing a cell with the “stated protein” from cells that do not have the “stated protein” (See Figure 2c), that is specifying a first light (GFP emitted light) associated with transfected cells and identifying the transfected cells (a noted region). The imaging device also determines the intensity of a second light emitted by the transfected cells as evidenced by Figure 2c which plots the intensity of second light of transfected cells in addition of second light relative to non-transfected cells.

With respect to claim 25, the system disclosed by the reference of Yao et al. is structurally capable of measuring intercellular reactions in which a plurality of cells stand adherent to one another. The same holds true for distinguishing between a region wherein the protein is “in a higher proportion than a stated standard”. Also, the device is structurally capable of detecting emitted light from a cell within a group of adherent cells wherein cells that do not emit light are also present. If not, the device of Yao et al. would not be capable of distinguishing between transfected cells and non-transfected cells. Note page 23 of the instant specification defines the “specifying means” structure as a fluorescent microscope that can detect fluorescent protein (GFP) and an image processing unit. The reference of Yao et al. discloses both of these structures. The instant specification defines the “selecting means” as a fluorescent microscope that can detect membrane-potential-sensitive fluorescent dye and an image-processing unit. The reference of Yao et al. discloses both of these structures as well. As a result, the reference of Yao et al. structurally meets the instant claim language since the structures are the same and the device would be capable of being used in the manner intended by preamble of the claim.

The claims holds true for independent claim 30.

With respect to claims 26 and 31, the system inherently includes a chemical-substance introduction means for introducing substances which target the “stated protein”. If not, the norepinephrine and forskolin required of Example 1 could not have been added to the cell culture.

With respect to claims 27 and 33, the second light intensity is sampled over constant time as evidenced by the plot generated in Figure 2C.

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With respect to claims 28 and 34, the system is structurally capable of detecting the intensity of a first light emitted by a fluorescent protein expressed together with the “stated protein” and a second light emitted from a fluorescent probe as evidenced by the GFP and Fura-2 of Example 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 29 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yao et al.(US 2003/0100059) in view of Hirose et al.(US 5,811,251).

The reference of Yao et al. has been discussed above.

Claims 29 and 41 differ by reciting that the photo-detection system includes a cooled CCD camera.

The reference of Hirose et al. discloses that it is known in the art of cell detection and imaging to employ cooled CCD cameras (See column 6, lines 27-51).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a cooled CCD camera in the imaging system of the primary reference for the known and expected results of increasing the detection sensitively of the imaging system.

Response to Arguments

10. With respect to the rejection of Claims 25-31, 33, 34, 36, 38 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, Applicants argue (See pages 9-10 of the response filed 2/21/2007) that the rejection has been overcome because claims 38 and 39 have been cancelled and because claims 25, 27-30, 33 and 34 have been amended to reduce “means-type” features.

In response, while the rejection of claims 38 and 39 has been rendered moot, claims 25, 27-30, 33 and 34 remain rejected because merely changing “means” to “member” is not sufficient to cure the deficiencies previously discussed in the last office and above in the rejection under 35 USC 112, second paragraph. Note the claims including the language “member” rather than “means” have been construed as means-plus-function limitations invoking 35 U.S.C. 112, sixth paragraph since the claimed limitations were described in terms of their function not their mechanical structure.

11. With respect to the rejection of Claims 25-31, 33, 34, 36, 38 and 39 under 35 U.S.C. 102(e) as being anticipated by Yao et al.(US 2003/0100059), Applicants argue (See pages 10-11 of the response filed 2/21/2007) that the reference of Yao et al. does not teach or suggest at least the features of the newly recited “extracting members” and “specifying member” that detects first light emitted from the specimen that includes “noted region” where the cell(s) emitting the first light and cell(s) emitting no first light” are present, and the features of “selecting means” that detects second light emitted from the “noted region”. Applicants stress that the reference of Yao et al. only focuses on cells having the protein and detecting the second light emitted only from such cells.

In response, Applicants’ comments are not found to be persuasive because the Examiner is of the position that the device disclosed by the reference of Yao et al. is structurally the same as that of the instant claims. They both include optical excitation and detection systems for exciting and detecting the same wavelengths of light and employ image capture and processing devices. A recitation of the intended use of the claimed invention must result in a structural

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difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant application, the reference of Yao et al. is structurally capable of performing the intended use recited in the instant claims. Applicants' comments focus on how the method performed in the instant application is different from the method performed in the Yao et al. reference yet are silent as to how the instant device "structurally" defines over the device of Yao et al. Note, if clumps of cells (See Figures 3A and 3B of the instant application) were employed in the device of Yao et al., the device of Yao et al. would be capable of identifying the noted regions based on the first light and distinguishing between noted regions with the protein and without the protein based on the detected second light over time. Furthermore, in view of the indefiniteness of the instant claim language, it is not clear what, if any, structural differences exist between the instant invention and the device of the reference of Yao et al. other than the intended use of the device. Additionally note Figure 2B of the reference of Yao et al. which depicts "noted regions" of cells including the stated protein among cells which stand adherent to one another.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner

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Primary Examiner
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WHB